

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re the Application of **Ernest Arenas, et al.**

Application No. 09/980,913

Attorney Docket No. 0380-P02709US0

Filed: May 21, 2002

For: MATERIALS AND METHODS RELATING TO
NEURONAL DEVELOPMENT

Examiner: Gerald G. Leffers Jr.

Group Art Unit: 1636

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)

I hereby certify that this Correspondence is being deposited on the date identified below with the United States Postal Service as first-class mail in an envelope properly addressed to Mail Stop, COMMISSIONER FOR PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450.

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97**

In accordance with the provisions of 37 C.F.R. §1.56, Applicant hereby submits the attached Form PTO-1449 listing additional references which the Patent Examiner is requested to consider and make of record in the above-identified application. Copies of each of the listed references are enclosed herewith. This submission is believed to be in full compliance with the requirements of 37 CFR §§1.97 and 1.98.

In accordance with 37 C.F.R. §1.97(c), enclosed herewith is the required fee of \$180.00, as set forth in 37 C.F.R. §1.17(p).

In the opinion of the undersigned, the references submitted herewith, together with those previously submitted with the Information Disclosure Statement filed July 31, 2003 and the Supplemental Information Disclosure Statement filed January 15,

2004, are the most pertinent of which the undersigned is aware. However, no representation is made or intended that more pertinent references do not exist.

In the event that the fee required in connection with this submission is not enclosed, the Commissioner is authorized to charge such fee or credit any overpayment to the account of the undersigned attorneys, Account No. 04-1406. A Fee Transmittal sheet is enclosed in duplicate.

This submission is not an admission that the references listed on the attached Form PTO-1449 constitute prior art against the claims of this application.

The Examiner is respectfully requested to confirm receipt and consideration of the cited references by initialing and returning a copy of the attached Form PTO-1449 in accordance with MPEP §609.

Favorable consideration of this application is again respectfully requested.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN
A Professional Corporation
Attorneys for Applicant(s)

By Patrick J. Hagan
Patrick J. Hagan
PTO Registration No. 27,643

Telephone: (215) 563-4100

Facsimile: (215) 563-4044

Enclosures - Form PTO-1449

Copies of references listed on PTO - 1449



TRANSMITTAL

Complete if known

Application Number: 09/980,913

Filing Date: May 21, 2002

First Named Inventor: Ernest Arenas, et al.

Title: Materials and Methods Relating to Neuronal Development

TOT. AMT. OF PAYMENT: (1) + (2) + (3) = \$ 180.00

Our File No.: 0380-P02709US0

METHOD OF PAYMENT (check one)

☒ Authorization is hereby granted to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account 04-1406.

☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims.

☒ Any patent application processing fees under 37 C.F.R. § 1.17

Any extensions of time that are required to maintain this application in a pending status, if not included herewith, are hereby requested. Authorization is hereby granted to charge such extension fees to Deposit Account No. 04-1406. Two copies of this transmittal are enclosed for accounting purposes.

☒ Payment enclosed: \$180.00

FEE CALCULATION

1. FILING FEE

Fee Description	Fee Paid
Utility filing fee	_____
Design filing fee	_____
Plant filing fee	_____
Reissue filing fee	_____
Provisional filing fee	_____
SUBTOTAL (1)	\$ 0.00

2. CLAIMS

	Extra	Fee	Fee Paid
Total Claims Presented _____			
(a)			
Independent Claims Presented _____			
(b)			
Multiple Dependent Claim (first presentation) _____			

(a) Enter 20 or number previously paid for

(b) Enter 3 or number previously paid for

SUBTOTAL (2) \$ 0.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Fee Description	Fee Paid
Surcharge-late filing fee or oath	_____
Surcharge - late provisional filing fee or cover sheet	_____
Non-English specification	_____
For filing a request for reexamination	_____
Requesting publication of SIR prior to Examiner action	_____
Requesting publication of SIR after Examiner action	_____
Extension for response within first month	_____
Extension for response within second month	_____
Extension for response within third month	_____
Extension for response within fourth month	_____
Notice of Appeal	_____
Filing a brief in support of an appeal	_____
Request for oral hearing	_____
Petition to institute a public use proceeding	_____
Petition to revive unavoidably abandoned application	_____
Petition to revive unintentionally abandoned application	_____
Issue fee	_____
Advance Order (10 copies)	_____
Publication Fee	_____
Petitions to the Commissioner	_____
Petitions related to provisional applications	_____
Submission of Information Disclosure Stmt.	180.00
Recording each patent assignment per property (times number of properties)	_____
Filing a submission after final rejection (37 CFR 1.129(a))	_____
For each additional invention to be examined (37 CFR 1.129(b))	_____
Other fee (specify) _____	_____

SUBTOTAL (3) \$180.00

Submitted By:

Typed or


Printed Name Patrick J. Hagan Reg. Number 27,643

Signature Patrick J. Hagan

Date November 12, 2004

Deposit Account User ID

04-1406

 <div style="text-align: center; font-size: 24px; font-weight: bold; margin-top: 10px;">FEE TRANSMITTAL</div>	Complete if known	
	Application Number: 09/980,913	
	Filing Date: May 21, 2002	
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METHOD OF PAYMENT (check one)	FEE CALCULATION (continued)																																																								
<input checked="" type="checkbox"/> Authorization is hereby granted to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account 04-1406. <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Any filing fees under 37 C.F.R. §1.16 for the presentation of extra claims. <input checked="" type="checkbox"/> Any patent application processing fees under 37 C.F.R. §1.17 </div> <p>Any extensions of time that are required to maintain this application in a pending status, if not included herewith, are hereby requested. Authorization is hereby granted to charge such extension fees to Deposit Account No. 04-1406. Two copies of this transmittal are enclosed for accounting purposes.</p> <input checked="" type="checkbox"/> Payment enclosed: \$ <u>180.00</u>	3. ADDITIONAL FEES <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; font-size: 10px;">Fee Description</th> <th style="text-align: right; font-size: 10px;">Fee Paid</th> </tr> </thead> <tbody> <tr><td>Surcharge-late filing fee or oath</td><td style="text-align: right;">_____</td></tr> <tr><td>Surcharge - late provisional filing fee or cover sheet</td><td style="text-align: right;">_____</td></tr> <tr><td>Non-English specification</td><td style="text-align: right;">_____</td></tr> <tr><td>For filing a request for reexamination</td><td style="text-align: right;">_____</td></tr> <tr><td>Requesting publication of SIR prior to Examiner action</td><td style="text-align: right;">_____</td></tr> <tr><td>Requesting publication of SIR after Examiner action</td><td style="text-align: right;">_____</td></tr> <tr><td>Extension for response within first month</td><td style="text-align: right;">_____</td></tr> <tr><td>Extension for response within second month</td><td style="text-align: right;">_____</td></tr> <tr><td>Extension for response within third month</td><td style="text-align: right;">_____</td></tr> <tr><td>Extension for response within fourth month</td><td style="text-align: right;">_____</td></tr> <tr><td>Notice of Appeal</td><td style="text-align: right;">_____</td></tr> <tr><td>Filing a brief in support of an appeal</td><td style="text-align: right;">_____</td></tr> <tr><td>Request for oral hearing</td><td style="text-align: right;">_____</td></tr> <tr><td>Petition to institute a public use proceeding</td><td style="text-align: right;">_____</td></tr> <tr><td>Petition to revive unavoidably abandoned application</td><td style="text-align: right;">_____</td></tr> <tr><td>Petition to revive unintentionally abandoned application</td><td style="text-align: right;">_____</td></tr> <tr><td>Issue fee</td><td style="text-align: right;">_____</td></tr> <tr><td>Advance Order (10 copies)</td><td style="text-align: right;">_____</td></tr> <tr><td>Publication Fee</td><td style="text-align: right;">_____</td></tr> <tr><td>Petitions to the Commissioner</td><td style="text-align: right;">_____</td></tr> <tr><td>Petitions related to provisional applications</td><td style="text-align: right;">_____</td></tr> <tr><td>Submission of Information Disclosure Stmt.</td><td style="text-align: right;">180.00</td></tr> <tr><td>Recording each patent assignment per property (times number of properties)</td><td style="text-align: right;">_____</td></tr> <tr><td>Filing a submission after final rejection (37 CFR 1.129(a))</td><td style="text-align: right;">_____</td></tr> <tr><td>For each additional invention to be examined (37 CFR 1.129(b))</td><td style="text-align: right;">_____</td></tr> <tr><td>Other fee (specify) _____</td><td style="text-align: right;">_____</td></tr> <tr> <td style="text-align: right; font-weight: bold; font-size: 12px;">SUBTOTAL (3)</td> <td style="text-align: right; font-weight: bold; font-size: 12px;">\$ <u>180.00</u></td> </tr> </tbody> </table>	Fee Description	Fee Paid	Surcharge-late filing fee or oath	_____	Surcharge - late provisional filing fee or cover sheet	_____	Non-English specification	_____	For filing a request for reexamination	_____	Requesting publication of SIR prior to Examiner action	_____	Requesting publication of SIR after Examiner action	_____	Extension for response within first month	_____	Extension for response within second month	_____	Extension for response within third month	_____	Extension for response within fourth month	_____	Notice of Appeal	_____	Filing a brief in support of an appeal	_____	Request for oral hearing	_____	Petition to institute a public use proceeding	_____	Petition to revive unavoidably abandoned application	_____	Petition to revive unintentionally abandoned application	_____	Issue fee	_____	Advance Order (10 copies)	_____	Publication Fee	_____	Petitions to the Commissioner	_____	Petitions related to provisional applications	_____	Submission of Information Disclosure Stmt.	180.00	Recording each patent assignment per property (times number of properties)	_____	Filing a submission after final rejection (37 CFR 1.129(a))	_____	For each additional invention to be examined (37 CFR 1.129(b))	_____	Other fee (specify) _____	_____	SUBTOTAL (3)	\$ <u>180.00</u>
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Submitted By:

Typed or


Printed Name Patrick J. Hagan Reg. Number 27,643

Signature Patrick J. Hagan

Date November 12, 2004

Deposit Account User ID

04-1406

 INFORMATION DISCLOSURE STATEMENT	<i>Complete if known</i>	
	Application Number: 09/980,913	
	Filing Date: May 21, 2002	
	First Named Inventor: Ernest Arenas, et al.	
	Group Art Unit: 1636	
	Examiner Name: Gerald G. Leffers Jr.	
SHEET 1 OF 2		Attorney Docket Number: 0380-P02709US0

UNITED STATES PATENT DOCUMENTS				
EXAMINER'S INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE MM-DD-YYYY	FIRST NAMED INVENTOR
	A1			

FOREIGN PATENT DOCUMENTS					
EXAMINER'S INITIALS	CITE NO.	DOCUMENT NUMBER	COUNTRY OR REGION	DATE OF PUBLICATION MM-DD-YYYY	FIRST NAMED INVENTOR OR APPLICANT
	B1				

OTHER PRIOR ART - NON-PATENT DOCUMENTS		
EXAMINER'S INITIALS	CITE NO.	Include name of the author (in Capital Letters), title of the article (when appropriate), title of the item(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C4	Haque NS, LeBlanc CJ, Isacson O. Differential dissection of the rat E16 ventral mesencephalon and survival and reinnervation of the 6-OHDA-lesioned striatum by a subset of aldehyde dehydrogenase-positive TH neurons. Cell Transplant. 1997 May-Jun;6(3):239-48.
	C2	Åkerud P., Canals J., Snyder E.Y. and Arenas E. (2001) Neuroprotection through delivery of GDNF by neural stem cells in a mouse model of Parkinson's disease. Journal of Neuroscience, 21: 8108-8118.
	C3	Åkerud P., Holm P.C., Castelo-Branco G., Sousa K., Rodriguez FJ. and Arenas E. (2002) Persephin-overexpressing neural stem cells regulate the function of nigrostriatal dopaminergic neurons and prevent their degeneration in a model of Parkinson's disease. Molecular and Cellular Neuroscience, 21: 205-222.
	C4	Freed CR, Leehey MA, Zawada M, Bjugstad K, Thompson L, Breeze RE. Do patients with Parkinson's disease benefit from embryonic dopamine cell transplantation? J Neurol. 2003 Oct;250 Suppl 3:III44-6.
	C5	Dunnett SB, Björklund A, Lindvall O. (2001) Cell therapy in Parkinson's disease - stop or go? Nat Rev Neurosci. 2001, 2(5):365-9.
	C6	Von Bohlen und Halbach OB, Schober A, Kriegstein K. Genes, proteins, and neurotoxins involved in Parkinson's disease. Prog Neurobiol. 2004 Jun;73(3):151-77.
	C7	Schwarz J. Rationale for dopamine agonist use as monotherapy in Parkinson's disease. Curr Opin Neurol. 2003 Dec;16 Suppl 1:S27-33.

EXAMINER'S SIGNATURE		DATE CONSIDERED	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw a line through citation if citation not in conformance and reference not considered. Include a copy of this form with next communication to applicant.

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SHEET 2 OF 2

C8	Gill SS, Patel NK, Hotton GR, O'Sullivan K, McCarter R, Bunnage M, Brooks DJ, Svendsen CN, Heywood P. Direct brain infusion of glial cell line-derived neurotrophic factor in Parkinson disease. Nat Med. 2003 May;9(5):589-95.
C9	Kordower JH, Emborg ME, Bloch J, Ma SY, Chu Y, Leventhal L, McBride J, Chen EY, Palfi S, Roitberg BZ, Brown WD, Holden JE, Pyzalski R, Taylor MD, Carvey P, Ling Z, Trono D, Hantraye P, Deglon N, Aebischer P (2000) Neurodegeneration prevented by lentiviral vector delivery of GDNF in primate models of Parkinson's disease. Science 290(5492): 767-773.
C10	Bjorklund A, Dunnett SB, Brundin P, Stoessl AJ, Freed CR, Breeze RE, Levivier M, Peschanski M, Studer L, Barker R. Neural transplantation for the treatment of Parkinson's disease. Lancet Neurol. 2003 Jul;2(7):437-45.
C11	Wagner J., Åkerud P., Castro D., Holm P C., Canals J M., Snyder E Y., Perlmann T. and Arenas E. (1999). Induction of a Midbrain Dopaminergic Phenotype in Nurr1-Overexpressing Neural Stem Cells. Nature Biotechnology, 17: 653-659
C12	Cochen V, Ribeiro MJ, Nguyen JP, Gurruchaga JM, Villafane G, Loc'h C, Defer G, Samson Y, Peschanski M, Hantraye P, Cesaro P, Remy P. Transplantation in Parkinson's disease: PET changes correlate with the amount of grafted tissue. Mov Disord. 2003 Aug;18(8):928-32.
C13	Hagell P, Brundin P. Cell survival and clinical outcome following intrastriatal transplantation in Parkinson disease. J Neuropathol Exp Neurol. 2001 Aug;60(8):741-52.
C14	Piccini P, Lindvall O, Bjorklund A, Brundin P, Hagell P, Ceravolo R, Oertel W, Quinn N, Samuel M, Rehn Crona S, Widner H, Brooks DJ. Related Articles, Links Abstract Delayed recovery of movement-related cortical function in Parkinson's disease after striatal dopaminergic grafts. Ann Neurol. 2000 Nov;48(5):689-95.
C15	KIRIK, D., et al., "Localized striatal delivery of GDNF as a treatment for Parkinson disease", Nature Neuroscience, vol. 7: p. 105-110, (2004).

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